seroconversion in said subject.

Claim 38: A method for determining seroconversion in a subject infected with hepatitis C virus, comprising: (i) incubating a sample taken from said subject, said incubating being carried out under reducing conditions with at least one polypeptide, the amino acid sequence of which is found in hepatitis C virus protein NS3 region, to determine binding of a hepatitis C virus specific antibody to said at least one polypeptide, and (ii) comparing results from (i) to results obtained at a previous point in time from said subject which were negative for presence of HCV antibody, wherein a difference in (i) as compared to results obtained from said patient at previous point in time which were negative is indicative of seroconversion.

Claim 39: A method for determining seroconversion in a subject, comprising: (i) incubating a sample taken from said subject, with a first solid phase bound polypeptide, and a second, labeled polypeptide which is in solution, wherein the amino acid sequence of said first and second polypeptides are found in hepatitis C virus protein NS3 region, said incubation being carried out under reducing conditions, to determine binding of a hepatitis C virus specific antibody to both of said first and second polypeptides, and (ii) comparing results from (i) to results obtained at a previous point in time from said subject which were negative for presence of HCV antibody, wherein a difference in (i) as compared to results obtained from said patient at previous point in time which were negative is indicative of seroconversion.

REMARKS

Claim 27 is amended, and claims 38 & 39 are added. In accordance with 37 CFR §1.121(h), a showing of changes for the amendment to claim 27 accompanies this amendment.

For support for claims 38 & 39, the examiner's attention is directed to pages 7-9 of the specification.

With respect to the specification objection, a replacement page 4 of the claims is attached.

With respect to the objections to claim 27 under 35 U.S.C. §112, second paragraph, "early" has been deleted from the claim, rendering the rejection moot.

The examiner objects to the use of the term "seroconversion" as being vague without some comparison steps. Attached hereto are copies of Barrera, et al, "Viral Hepatitis and Liver Disease", pp. 350-1 (1994), Hino, Intervirology 37:77-86 (1994). Okamoto, et al, Japan. J. Exp. Med. 60(4)223-233 (1990). All evidences of knowledge of the term at the time the application was filed. That is all the statute requires. "Derived" has been amended as well.

Claims 27-36 were rejection on obviousness type double patenting, a terminal disclaimer

is provided herewith, with the appropriate fee.

With respect to the rejection of claim 27 under 35 U.S.C. §102(b)/103, applicants contend that the claim is not incomplete, as explained supra, anticipation does not lie. Hence the rejection is properly framed as one under 35 U.S.C. §103.

The Japanese reference does not teach or suggest seroconversion, which is an art defined term. What the Japanese reference teaches is that one can achieve improved dilution sensitivities. In other words, if reducing conditions were used, diluted sera was more reactive, and the immune reactivity was increased. Such is not a method for detecting seroconversion. In the Japanese reference, the samples have already "converted."

The reference falls short of the teachings that are necessary to establish a prima facie case, and obviousness has not been made out.

In view of the foregoing and the attachments, withdrawal of the rejections, and allowance of the application is believed proper and is urged.

Respectfully submitted,

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VIA FIRST CLASS MAIL

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to Commissioner of Patents and Trademarks, Washington, D.C. 20231 on September 17, 2002.

Signature: Laura Ades Date: 9/17/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	**Christoph Seidel, et al.**
Serial No.:	**09/896,032**
Filed:	**June 29, 2001**
For:	**METHOD FOR DETERMINING EARLY HCV SEROCONVERSION**
Group Art Unit:	**1648**
Examiner:	**D.C. Wortman**

September 17, 2002

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

SHOWING OF CHANGES

Claim 27 (Amended): A method for [early] recognition of seroconversion, comprising: incubating a sample taken from a subject, under reducing conditions which prevent formation of covalent, cross linked molecular aggregates, with at least one polypeptide [derived from] consisting of an amino acid sequence found in a hepatitis C virus protein NS3 region which is immunologically reactive with said hepatitis C virus specific antibody, and determining binding of said antibody to said polypeptide to recognize seroconversion in said subject.

Respectfully submitted,

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